Advancing Pandemic and Seasonal Influenza Vaccine Preparedness and Response: Harnessing Lessons from the Efforts Mitigating the COVID-19 Pandemic

Report Highlights

Vaccine Research and Development to Advance Pandemic and Seasonal Influenza Preparedness and Response: Lessons from COVID-19

This report provides recommendations on how to leverage knowledge gained from the COVID-19 pandemic to develop improved influenza vaccines, identify new and improved vaccine platforms, improve regulatory practices for a pandemic scenario, and expand and improve manufacturing capacity.

The committee concluded that novel vaccine platforms have the potential to improve the effectiveness and speed with which influenza vaccines are produced, but significant R&D funding is necessary to develop those novel platforms and technologies. Innovations in vaccine technology driven by COVID-19 will also require building new production capacity. In addition to basic and translational science, clinical science for

Co plete List of Reco endation

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2.1: The U.S. Department of Health and Human Services, through the National Institute of Allergy and Infectious Diseases, the Biomedical Advanced esearch and Development Authority, and the U.S. Department of Defense, as well as other correspo governmental and funding agencies domestically and abroad, should invest, proportionate to the enormous costs o and translational research to reveal a diverse array of influenza vaccines, using different platfo viral targets, adjuvants, and delivery systems. This will allow selection of the candidates most fit for purpose to be brought to authorization and sufficient production and distribution to optimize the control of influenza across divan

The International Coalition of Medicines egulatory Authorities and the World Health Organization (Global Advisory Committee on Vaccine Safety) should ensure international coordination and collaboration on the timely and transparent review of vaccine safety data during epidemics and pandemics to support real-time decision making about the use of vaccines. Safety data should be made available to support country-level benefit-risk assessments, particularly for low- and middle-income countries relying on regional data from sentinel sites conducting safety surveillance.

4 : The U.S. Department of Health and Human Services and the World Health Organization should develop a plan for a sufficient and self-sustainable global supply of influenza vaccines for pandemics. This includes

4 : Vaccine manufacturers should take a risk-based approach to pandemic influenza preparedness. This approach would be most effective if incentivized, and could include

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5.1: The U.S. Food and Drug Administration and other national regulators (e.g., European Medicines Agency) working with the scientific community and pharmaceutical industry should enhance comprehensive guidance for the development of influenza vaccines on novel platforms through emergency use authorization to full licensure. This guidance should provide pathways for seasonal and pandemic influenza.

5.2: The U.S. Food and Drug Administration and other national regulators (e.g., European Medicines Agency) should commit to transparency in the oversight of clinical trials, review of data, authorization, and approval of pandemic influenza vaccines, including the release of facility inspection findings, clinical trial protocols, and clinical data that are the basis of decision making. egulators should convene independent advisory committees to systematically review data, make recommendations, and build public understanding and confidence prior to the authorization or approval of novel vaccines.

5. : The World Health Organization and the International Coalition of Medicines egulatory Authorities should encourage and support the coordination between regulatory and public health agencies (e.g., the U.S. Centers for Disease Control and Prevention, the European Centre for Disease Prevention and Control, the China Center for Disease Control and Prevention, and the Africa Centres for Disease Control and Prevention) when announcing different decisions on the same or similar vaccines, to explain the different ievdnc, praf

- End-to-end visibility of critical inputs: in collaboration with the World Trade Organization, the Coalition for Epidemic Preparedness Innovations, the Developing Countries Vaccine Manufacturers Network, and the International Federation of Pharmaceutical Manufacturers & Associations, evaluate a means to define, identify, and track (e.g., through barcodes and blockchain technologies) the global real-time availability of potentially supply-constrained critical inputs necessary to manufacture vaccines for pandemic influenza, known as the essential global commons list for pandemic influenza vaccine manufacturing.
- esiliency assessment and analysis: in collaboration with other U.S. agencies (including the Office of Science and Technology Policy, the U.S. Trade epresentative, and the U.S. Agency for International Development) provide technical and resourcing support for the committee's recommended task force to forecast supply and demand of critical inputs, including workforce personnel and training needs for pandemic influenza vaccine manufacturing, and perform a resiliency assessment of the current end-to-end network to identify vulnerabilities in physical inputs, as well workforce gaps, that may impede pandemic influenza vaccine manufacturing. o

- **4.1(a)**: HHS, its global counterparts, and relevant global funders and stakeholders should encourage attention to operational considerations up-front when funding vaccine development.

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6.4: The World Bank should develop a global indemnification mechanism that can be applied to all vaccines with World Health Organization (WHO) em[illegible] listing or prequalification, regardless of the mechanism (pooled or bilateral) or financing used to procure the va[illegible]

6.5(a): The Department of Health and Human Services and the Food and Drug Administration should investigate the barriers to public transparency of vaccine clinical trial protocols during a public health emergency and evaluate measures, including legislation, to remove these barriers..

6.5(b): The World Health Organization should support an independent after-action review of its emergency use listing procedures, including learning from the COVID-19 experience, to make recommendations regarding appropriate process structure, staffing, and resourcing for surge capacity needed for expedited reviews during a future pandemic.

6.5(c): The Department of Health and Human Services, along with the World Health Organization, should support the creation of a network of inspectors to conduct rapid inspections of vaccine manufacturing plants during a pandemic to ensure vaccine quality, which may include providers of assays, technical experts, and lot comparability in secondary manufacturing

Public Health Lessons for Non-Vaccine Influenza Interventions: Looking Past COVID-19

2.1: The World Health Organization, the World Bank, and regional public health organizations should work collaboratively with countries (particularly for low- and middle-income cou[illegible] those with extensive animal-human interfaces) to build sustainable capacity for routine surveillance in anima[illegible], and domestic), and develop and support interagency One Health platforms.

2.2: Countries should institute surveillance as the backbone of their health care systems, which should include submitting aggregated clinical data feeding into public health agencies. To ensure that policy makers have access to accurate, timely, and comprehensive risk assessments, national authorities—with the advice and assistance of regional and global public health agencies—should establish more robust surveillance systems, involving public hospitals and academic medical centers, manufacturers of diagnostics, and social network platforms. Epidemiologists should be alert to potential ascertainment biases regarding sampling frames and other methodological pitfalls, account for such biases during analysis and interpretation of the data and should notify authorities to take these biases into account and seek support for improving surveillance methods to better achieve representativeness and sufficient geographical coverage.

2.[illegible]: National public health agencies should both strengthen the capabilities of local and provincial authorities to accurately, rapidly, and transparently report data about novel agents and strains and improve their own reporting of data to such regional organizations and global bodies as the World Health Organization and the One Health Tripartite. The global bodies should develop methods to harmonize data from multiple sources, to enable prompt dissemination of useful, comprehensive data, especially to the national and regional organizations that have contributed to the data pool. Organizations to which data are submitted at all levels should work toward removing barriers and disincentives to making full and accurate reports.

2.4: The World Health Organization and regional disease control agencies (e.g., European Centre for Disease Prevention and Control, Africa C[illegible] countries, and national governments should work with subnational [illegible] collection, and s[illegible]

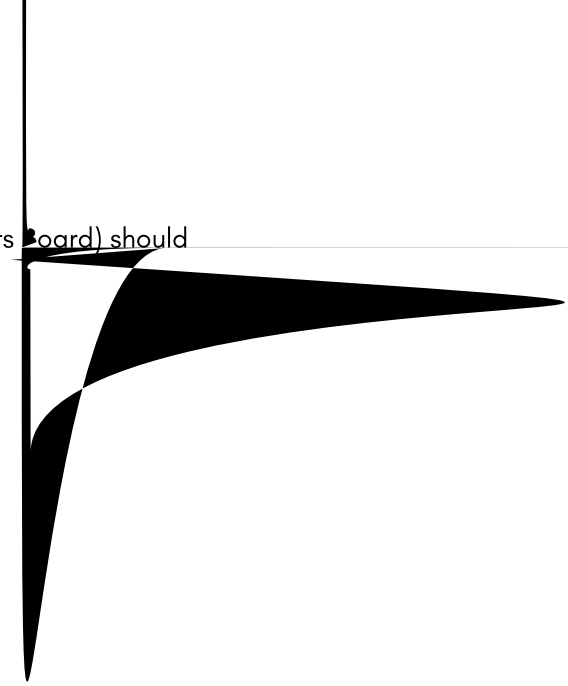
[illegible].1: The World He[illegible] during a panden[illegible]

The World H[illegible]

- Take the systemic factors, such as race and socioeconomic disadvantages that affect the health of affected populations into consideration and leverage behavioral health research and marketing tactics when developing and implementing public health interventions;
- Demonstrate, in their behavior, adherence to non-vaccine measures to prevent influenza in order to promote public trust in, and uptake of these measures;
- Engage the community—including grassroots organizations, spiritual leaders, teachers, and mass a

- Who will evaluate guidance from global and national health organizations and from professional societies in order to define evid

- **(a).** The G7 and G 0 member nations (e.g., through the Global Health Threats oard) should



- **(a).** Identify o